

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed September 14, 2010. Claims 1, 3-6, 21-28, and 31-42 were pending and rejected in view of cited art. Claim 22 are cancelled and claims 1, 23, 24, 34, and 39 are amended. Claims 1, 3-6, 22-28, and 31-42 remain pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

A. EXAMINER'S INTERVIEW

Applicant's express their appreciation to the Examiner for conducting an interview with Applicant's representative on 13 January 2011. The substance of the interview is included in this response.

B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claims 22-24 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claim 22 has been cancelled and claims 23 and 24 amended to more clearly define the claimed invention and corrected any unclear grammatically and confusing language. In view of the same Applicant respectfully requests withdrawal of the rejection under Section 112.

C. PRIOR ART REJECTIONS

As presented herein for reconsideration (see independent claim 1, as exemplary), the stent system comprises "a stent having an exterior surface, an interior surface, and side surfaces." Of the stent surfaces "at least one of the surfaces is roughened and including sandblasting particles"

that are "incorporated into the roughened surface." Disposed on "at least one of the roughened surfaces" is "a polymer-free external coating" that includes "a therapeutic agent."¹

The Office Action rejected claims 1, 3, 5-6, 21-28, 34-35, 37-40 and 42 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,843,172 (*Yan*) in view of U.S. Patent No. 6,174,329 (*Callol*), with supporting evidence from U.S. Patent No. 6,805,898 (*Wu*). Claims 4, 31-33, 36, and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Yan* in view of *Callol*, further in view of U.S. Publication No. 2002/0082679 (*Sirhan*).

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Yan*, either singly or in combination with any other cited references of record.² In accordance with Applicant's understanding, *Yan* teaches a porous medicated stent that is sintered together from a plurality of particles so as to be porous and have internal reservoirs. *Yan* does not teach or suggest a roughened surface that incorporates sandblasting particles, such as corundum sandblasting surfaces. Since the stents taught by *Yan* are porous, and thereby have an external surface of variable topology and have a roughened surface, there appears to be no reason to further roughen a roughened surface by sandblasting. Thus, there appears to be no reason for the surface of *Yan's* stent to incorporate "sandblasting particles", such as "corundum sandblasting particles."

To overcome the deficiency of *Yan*, *Callol* and *Wu* were cited for teaching sandblasting. *Callol* was cited for the proposition that it discloses "use of sandblasting as a suitable means for roughening a stent surface (col. 7 lines 23-27) in order to improve adhesion between layers" (Office Action, p. 4). *Wu* was cited for the proposition that it discloses "roughening surfaces using stand blasting [sic] and bead blasting" *Id.* That said, in accordance with Applicant's

¹ The other two independent claims (e.g. claims 34 and 39) are similar.

Claim 34 differs from claim 1 by adding the further limitation of "at least a portion of the roughened surfaces is repassivated and includes corundum sandblasting particles incorporated into the roughened surface."

Claim 39 differs from claim 1 by further limiting the surfaces of the stent to recite, in part, "a stent having a roughened and *annealed* exterior surface, a roughened and *annealed* interior surface, wherein at least a portion of the roughened surfaces is *repassivated* and includes *corundum sandblasting particles incorporated into the roughened surface*" (emphasis added).

Claims 34 and 39 should also be allowed for the same reasons as claim 1, since claims 34 and 39 merely add further limitations to those recited in claim 1.

² Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

understanding, none of these references teach or suggest incorporating "sandblasting particles" into the roughened surface, with the surface and the particles being coated with a "polymer-free external coating," notwithstanding the general discussion of using "sandblasting" to roughen the surface. For example, *Callol* teaches using "acid treatment, sandblasting, or similar methods" to "allow a mechanical interlocking between the substrate [the radiopaque layer] and the protective layer" (col. 7, ll. 24-26). No mention is made of using this technique for the base stent or that the substrate includes "sandblasting particles." In addition, *Wu* teaches that subsequent to blasting the stent, "the stent is removed from the mandrel and cleaned, for example, by immersion and sonication in an isopropyl alcohol bath for approximately 20 minutes" (col. 9, ll. 52-54). No mention is made of incorporating or including "sandblasting particles" in the roughened surface.

To further clarify the claimed invention independent claims 1, 34, and 39 have been amended to recite, in part, "at least one of the surfaces being roughened and including sandblasting particles incorporated into the roughened surface", "at least a portion of the roughened surfaces is repassivated and includes corundum sandblasting particles", and "at least a portion of the roughened surfaces is repassivated and includes corundum sandblasting particles", respectively. Applicant respectfully submits that *Yan*, *Callol*, *Wu*, and *Sirhan*, neither teach nor suggest the inclusion or incorporation of "sandblasting particles" into the roughened surface or that the roughened surfaces is "repassivated."

Accordingly, for at least the reasons noted, independent claims 1, 34, and 37 and the claims depending therefrom³ are neither anticipated nor made obvious by *Yan*, either singly or in combination with any other prior art of record⁴, and thus reconsideration and withdrawal of the rejection is respectfully requested.

³ Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 3-6, 21, 23-28, 31-33, 35-38, and 40-42, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicant thus does not acquiesce in any asserted rejections of the dependent claims 3-6, 21, 23-28, 31-33, 35-38, and 40-42.

⁴ *Sirhan* was cited as a secondary reference, in addition to *Callol* and *Wu*. *Sirhan* was cited as disclosing "use of tacrolimus as a suitable drug for therapeutic treatment" (Office Action, p. 5). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Yan*. Thus, even assuming *arguendo* that any of the

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 14th day of January, 2010.

Respectfully submitted,

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